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TITED STATES PATENT AND TRADEMARK OFFICE

Applicants ADEMARY : Bernard Conrad and Bernard Mach

U.S. Serial No. : 09/490,700

Filed: January 24, 2000

For : METHODS FOR DIAGNOSIS AND THERAPY OF

AUTOIMMUNE DISEASE, SUCH AS INSULIN DEPENDENT DIABETES MELLITUS, INVOLVING

RETROVIRAL SUPERANTIGENS

1185 Avenue of the Americas New York, New York 10036 April 26, 2000

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. § 1.56 and § 1.97(a)-(b) applicants would like to direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit 1) and attached hereto as Exhibits 2-14:

- 1. United States Patent No. 5,508,166, issued April 16, 1996, Tanno et al. (Exhibit 2):
- 2. PCT International Publication WO 93/23560, published November 25, 1993 (Exhibit 3);
- 3. PCT International Publication WO 95/11975, published May 4,

Bernard Mach and Bernard Conrad U.S. Serial No.: 09/490,700

Filed: January 24, 2000

Page: 2

1995 (Exhibit 4);

- 4. PCT International Publication WO 96/23076, published August
 1, 1996 (Exhibit 5);
- 5. PCT International Publication WO 96/35793, published November 14, 1996 (Exhibit 6);
- 6. PCT International Publication WO 97/22694, published June 26, 1997 (Exhibit 7);
- 7. Benoist and Mathis, *Retrovirus as trigger, precipitator or marker?" Nature 388: 833-834 (August 28, 1997) (Exhibit 8);
- 8. Bernard Conrad and Massimo Trucco, "Superantigens as Etiopathogenetic Factors in the Development of Insulin-Dependent Diabetes Mellitus", Diabetes/Metabolism Reviews 10(4): 309-338 (1994) (Exhibit 9);
- 9. Conrad, et al., "A Human Endogenous Retroviral Superantigen as Candidate Autoimmune Gene in Type I Diabetes" Cell <u>90</u>: 303-313 (July 25, 1997) (Exhibit 10);
- 10. Löwer, et al., "A General Method for the Identification of Transcribed Retrovirus Sequences (R-U5 PCR) Reveals the Expression of the Human Endogenous Retrovirus Loci HERV-H and HERV-K in Teratocarcioma Cells" Virology 192: 501-511 (1993) (Exhibit 11);
- 11. Löwer, et al., "Identification of a Rev-Related Protein by Analysis of Spliced Transcripts of the Human Endogenous Retroviruses HTDV/HERV-K" Journal of Virology, 141-149

Bernard Mach and Bernard Conrad U.S. Serial No.: 09/490,700 Filed: January 24, 2000

Page: 3

(January 1995) (Exhibit 12);

- 12. Ono, et al., "Nucleotide Sequence of Human Endogenous Retrovirus Genome Related to the Mouse Mammary Tumor Virus Genome" Journal of Virology, 589-598 (November 1986) (Exhibit 13); and
- 13. Walchner, et al., * Endogenous retroviral sequences as a pathogenic factor in systemic lupus erythematosus" Hautarzt 47: 502-509 (1996) (Exhibit 14).

Applicants point out that Walchner, et al. (Exhibit 14) and PCT International Publication WO 93/23560 (Exhibit 5), are not in the English language. However, the Walchner, et al. article includes an English summary and the German Publication of WO 93/23560 includes an English translation of the abstract.

The aforementioned references 1-13 (Exhibits 2-14) were cited by the International Searching Authority in the International Search Report, issued October 12, 1999 in connection with PCT International Patent Application No. PCT/EP98/04926. A copy of the International Search Report is attached hereto as Exhibit 15.

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Bernard Mach and Bernard Conrad U.S. Serial No.: 09/490,700

Filed: January 24, 2000

Page: 4

No fee is deemed necessary in connection with the filing of the Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents, Washington, D.C. 20231 4/26/00

John P. White Reg. No. 28,678 Date

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